UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FRED BERGMAN HEALTHCARE PTY LTD. and SIMAVITA (AUST) PTY LTD.,

Plaintiffs,

v.

SENECA SENSE TECHNOLOGIES INC.

Defendant.

Case No. 1:22-cv-02167

Jury Trial Demanded

PLAINTIFFS FRED BERGMAN HEALTHCARE PTY LTD.'S AND SIMAVITA (AUST) PTY LTD.'S
RESPONSE TO DEFENDANT'S OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

Pursuant to local patent rule 4.2(c) and the Court's Order dated September 30, 2024, Plaintiffs Fred Bergman Healthcare Pty Ltd. and Simavita (Aust) Pty Ltd., (collectively "Bergman" or "Plaintiffs") submit this responsive claim construction brief in response to Seneca Sense Technologies Inc.'s ("Seneca Sense" or "Defendant") opening claim construction brief, Dkt. No. 97 (Opening Brief). For the following reasons, the Court should adopt Plaintiffs' proposed constructions and reject the Defendant's constructions.

II. BACKGROUND

Plaintiffs filed suit against Defendant Seneca Sense alleging infringement of U.S. Patent No. 7,977,529 ("the '529 Patent"), which is titled "Incontinence Management System and Diaper." JA0001. Claim 1 is the only independent claim of the '529 Patent, and all terms in dispute are found within Claim 1. Claim 1 recites:

> 1. A moisture monitoring system for monitoring wetness in one or more absorbent articles, the system including:
>
> an input for receiving one or more sensor signals indicative of a presence of wetness in an absorbent article;
>
> a processor; and
>
> user interface for communicating with a user of the system;
>
> wherein the processor executes an algorithm to analyze the one or more sensor signals by applying the one or more received sensor signals to a pre-determined mathematical model to characterize a wetness event in an absorbent article; and
>
> wherein the system has devised the pre-determined mathematical model using sensor signal data previously received by the system, the mathematical model representing a relationship between one or more variables obtainable from the received sensor signals and a characteristic used to characterise a wetness event.

JA0023 at 19:43-59.

A. Written Description of the '529 Patent

The '529 Patent is directed to an incontinence management system for monitoring wetness in one or more absorbent articles. The system requires an input, a processor, and a user interface. *Id.*; *see also* JA0015 at 3:17-23. The processor can "execute an algorithm" or set of instructions "to devise automatically a mathematical model for characterizing a wetness event in an absorbent article." *Id.* at 3:24-26. The processor "appl[ies] sensor signals … to determine one or more parameters suitable for use in a mathematical model …" *Id*. at 3:35-38. Sensors may be used to characterize conductivity, temperature, location, pH, pressure, odor, gas, or even the presence of biological and chemical markers in a wetness event. *Id.* at 3:38-44.

Using conductivity as a nonlimiting example, in one embodiment "[w]hen an electrolyte such as urine contacts the conductive elements" or sensors "in sufficient quantity, a conductive bridge is formed between the elements and this can be detected by monitoring one or more electrical characteristics of the elements such as resistance or conductance, capacitance or the like." JA0020 at 13:56-61. The system uses sensor signal data, such as but not limited to the "area under a sensor signal curve, highest sensor signal value in a predetermined time period, maximum value of a leading edge of the sensor signal, rate of decay of sensor signal after a leading edge," etc., JA0017 at 8:49-61, to "derive variables from the sensor signal for use by the algorithm to determine one or more parameters suitable for use in a mathematical model for characterising a wetness event," JA0015 at 3:35-38.

In a preferred embodiment, the processor is trained to "reconfigur[e] the mathematical model" until there is a "satisfactory correlation between [(i)] the estimates produced using the sensor signals and reconfigured mathematical model and [(ii)] the observation data…" JA0015 at 4:25-35. In one embodiment, training involves "using [a] particular individual, [a] different sensor

type, or [a] different absorbent article type, monitoring wetness at regular intervals by obtaining sensor signals and obtaining observation data," and "linear regression techniques" can be used "to determine one or more new parameters for the mathematical model." JA0015 at 4:27-39. "Training may involve continually monitoring sensor signals for indications of wetness and upon every variation in sensor values, obtaining observation data by changing the pad, examining the pad and weighing the pad." JA0018 at 9:10-13. "Additional observation data may be collected such as amount and time of fluid and food intake, as these variables influence the patient's continence function and are therefore potentially influential variables in the mathematical model." *Id.* at 9:13-17. During the training period, "the processor executes an algorithm performing a regression analysis to formulate parameters for the mathematical model," and "these parameters are fed back into the mathematical model and a confidence level is determined." *Id.* at 9:18-23. "If the confidence level is acceptable (e.g. above R^2-0.6) then the parameters are accepted and the model updated." If the confidence level is not acceptable, further training and regression analysis is performed "until an acceptable confidence level is reach." *Id.* at 9:27-31.

Using Eq. 1 as a nonlimiting example, the specification describes a pre-determined mathematical model that factors patient weight and age in addition to the area under a sensor signal curve to determine an estimated volume. *See*, *Id.* at 10:5-11. "[T]he processor executes an algorithm to compare the estimated volume with a pre-determined threshold level." *Id.* at 10:16-17. "Eq. 1 is just one example of a mathematical model which may be used to characterise wetness events." *Id.* at 10:12-14. In other words, the system is agnostic to the model used. In fact, the specification discloses that "[t]he models may be embodied in any form including mathematical models as described above [(i.e., databases)], graphs or look up tables." JA0021 at 15:56-62.

B. Prosecution History of the '529 Patent

The application giving rise to the '529 Patent initially received a single substantive office action rejecting claim 1 as anticipated in light of Bergman, WO 96/14813 ("Bergman") and alternatively was deemed obvious over Bergman in view of Panopoulos, US 2004/0220538 ("Panopoulos"). JA0790-JA0795. Original claim 1 was amended in response to this rejection as follows:

> 1. (Currently amended) A moisture monitoring system for monitoring wetness in one or more absorbent articles, the system including:
>
> an input for receiving one or more sensor signals indicative of a presence of wetness in an absorbent article;
>
> a processor ~~for processing the one or more sensor signals and for performing an analysis of the signals to characterise wetness events occurring in an absorbent article~~; and
>
> user interface for communicating with a user of the system;
>
> wherein the processor executes an algorithm to analyze the one or more sensor signals by applying the one or more received sensor signals to a pre-determined mathematical model to characterize a wetness event in an absorbent article; and
>
> wherein the system has devised the pre-determined mathematical model using sensor signal data previously received by the system, the mathematical model representing a relationship between one or more variables obtainable from the received sensor signals and a characteristic used to characterise a wetness event.

JA0830. Applicants argued against the anticipation rejection by briefly pointing out that Bergman did not teach each and every element of the claim 1 as amended. JA00841 ("To anticipate a claim, the reference must teach each and every element of the claim. Bergman does not disclose all the features of Claim 1 as amended."). Applicants then turned to the obviousness rejection.

Applicants first argued that Bergman did not teach the use of any mathematical model or previously received sensor signals to devise a mathematical model to characterize a wetness event, and further that a person having ordinary skill in the art ("POSA") would not have found the same to be obvious from the disclosure in Bergman. *See*, JA0843-44. Next, applicants acknowledged

the disclosure of an "algorithm" in Panopoulos, JA0844, but argued that the algorithm of Panopoulos "does nothing more than applying a conversion factor or interrogating a look up table to ascertain the usable data from the conditioned signal data," JA0845. In other words, "[t]here is no teaching or suggestion in Panopoulos that a mathematical model is determined *by the system*, based on previously received sensor data." *Id.* Applicants also pointed out that Panopoulos teaches away from amended claim 1 in that Panopoulos disclosed the use of alerts so that "a caregiver may change a diaper immediately thus minimizing contact of these contaminant with the skin immediately, thus eliminating diaper rash and other diseases…" JA0846 (applicant quoting Panopoulos, italics removed); *see also* JA0847 ("In fact, Panopoulos teaches against these determinations and use of mathematical models for making those determinations, since Panopoulos is directed to avoiding any lingering wetness in the diaper…"). Panopoulos is thus "contrary to the instant invention where sensor signals detecting [a] wetness in incontinence garments are processed to provide more detailed information about the wetness event and *not merely identify when the event has occurred for alerting a caregiver.*" JA0846 (emphasis added).

Subsequently, the examiner issued a notice of allowance. JA0851. Defendant misrepresents the prosecution history of the '529 Patent. *See* e.g., Opening Brief, p. 2 ("Over the five-year prosecution, claim 1 underwent significant revisions."). A review of the prosecution history will show the application giving rise to the '529 Patent received two restriction requirements before its one and only office action and was granted a term adjustment under 35 U.S.C. 154(d) of 823 days for Office delay during prosecution. JA0741-48 (Requirement for Restriction/Election of October 21, 2009); JA0774-80 (Requirement for Restriction/Election of April 28, 2010); JA0790-95 (Non-Final Office Action of June 8, 2010); JA0876 (Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)).

C. Summary of Defendant's Opening Brief

The Court should not be persuaded by Defendant's Opening Brief for several reasons including but not limited to the following. First, Defendant's indefiniteness argument is not based upon any applicable standards from either the Federal Circuit or the Supreme Court and misconstrues case law in its favor. In fact, the case law cited by Defendant when compared to the facts of this case does not support a finding of indefiniteness. Second, Defendant's constructions improperly import limitations from preferred embodiments into claim 1 when the specification supports a broader construction. *See Liebel–Flarsheim Co. v. Medrad, Inc.,* 358 F.3d 898, 906 (Fed. Cir. 2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'") (citing *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002)). Third, Defendant misconstrues the prosecution history by ignoring the prior art the applicants sought to traverse to further its argument that details found within preferred embodiments are necessary to construction.

III. LEVEL OF SKILL IN THE ART

Plaintiffs do not oppose Defendant's proposed level of ordinary skill in the art.

IV. ARGUMENT

A. Term 1: "pre-determined mathematical model"

Plaintiffs' Construction	Defendant's Construction
No construction necessary, plain-and-ordinary meaning.	(i) Indefinite, or alternatively, (ii) "one or more equations with parameters that are calculated and recalculated based on sensor signal data"

i. The Claim "Pre-Determine Mathematical Model" is Not Indefinite

The term "pre-determined mathematical model" is not indefinite because the specification

of the '529 Patent sufficiently describes the scope of "pre-determined mathematical model." 35 U.S.C. § 112 requires patents to "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." To satisfy this requirement, claims must "inform [a POSA] about the scope of the invention with reasonable certainty" when "viewed in light of the specification and prosecution history." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 2129 (2014). While "absolute precision" is not required, Section 112's requirement is a "'delicate balance' between 'the inherent limitations of language' and providing 'clear notice of what is claimed.'" *Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017) (citing *Nautilus*, 134 S.Ct. at 2129). "A claim term can be rendered definite using examples in the specification, but those examples must provide some objective criteria by which a POSA can determine the scope of a claim with reasonable certainty." *Mantissa Corp. v. First Fin. Corp.*, No. 17 C 9174, 2022 WL 1487577, at *6 (N.D. Ill. May 11, 2022), aff'd, No. 2022-1963, 2024 WL 607717 (Fed. Cir. Feb. 14, 2024) (citing *Sonix Tech. Co., Ltd.*, 844 F.3d at 1379 (Fed. Cir. 2017)). Conversely, "[t]he mere existence of examples in the written description will not always render a claim definite." *Mantissa Corp.,* 2022 WL 1487577, at *6 (citing *Sonix*, 844 F.3d at 1379). Defendant must prove indefiniteness with clear and convincing evidence. *Sonix*, 844 F.3d at 1377.

Defendant argues the objective boundaries are "*unclear,*" unless "the claims were limited to the specific example of a 'pre-determined mathematical model' provided in the specification." Opening Brief, pp. 4, 6 (emphasis original). However, a POSA would understand from the specification and claim 1 that the "pre-determined mathematical model" includes variables based on sensor signal data. Further, a POSA would understand from the specification and claims that the pre-determined mathematical model may optionally include variables based on data collected

by the user-monitor[1] that is relevant to the user-patient's voiding habits and/or data relevant to the absorbent article. Lastly, a POSA would understand from the specification that the system and "pre-determined mathematical model" are agnostic to the parameters initially selected for each variable because through a regression analysis the parameters are adjusted. Based on these clear teachings, the term "pre-determined mathematical model" is not indefinite and should be given its plain and ordinary meaning.

a. "Pre-Determined Mathematical Model" Includes a Variable Based on Sensor Signal Data

The specification repeatedly describes that the "pre-determine mathematical model" includes at least one independent variable derived from sensor signal data. E.g., JA0015 at 3:19-21 & 3:35-38; JA0017 at 8:12-21. Indeed, the specification discloses a specific example of a pre-determined mathematical model to estimate volume of exudate using the equation:

$$\text{Volume} = 0.3 \times (\text{Profile\_Area}) + 2.4 \times (\text{Patient\_Weight}) - 0.6 \times (\text{Patient\_Age}) \quad \text{(Eq 1)}$$

JA0018 at 10:1-15 (describing Eq. 1 including as independent variable "Profile_Area" representing the area under a sensor signal curve). The specification teaches that sensors in the absorbent article are capable of sending a signal in response to the "conductivity," "temperature," "location," and/or "pH" of the exudate, as well as the "pressure," "odour," "gas," "blood," "biological marker[s]," and/or "chemical marker[s]" of, caused by, coming from, or within the exudate. JA0015 at 3:38-44; *see also*, e.g., JA0016 at 5:30-33; JA0017 at 7:52-8:11; JA0020 at 13:56-14:3. As a nonlimiting example, the specification discloses "an electrolyte such as urine"

[1] Defendant uses the term "user" to describe the individual wearing the absorbent article. As used in the specification, "user" is used loosely and understood by surrounding context to be either the individual wearing the absorbent article (hereafter for clarity "user-patient") or the individual monitoring the user interface such as a caretaker (hereafter for clarity "user-monitor").

can cause a change in the "electrical characteristics" between "conductive elements" that is measurable as a sensor signal. JA0020 at 13:56-61. "[V]ariables derived from the sensors signals" include but are not limited to "area under a sensor signal curve," the "highest sensor signal value in a predetermined time period," and the "maximum value of a leading edge of the sensor signal." JA0015 at 3:46-53 (other nonlimiting examples provided). The specification then discloses the use of at least one variable derived from sensor signals to characterize the wetness event. For example, the area under a sensor signal curve is used to estimate the volume of a wetness event in Eq. 1. JA0018 at 10:6-11. In turn, claim 1 of the '529 Patent requires the model to represent a relationship between a variable obtained from a sensor signal, such as the area under a signal curve, and a characteristic used to characterize a wetness event, such as estimated volume of the exudate. JA0023 at 19:56-59. Based on the specification and claim 1, a POSA would understand that the "pre-determined mathematical model" includes an independent variable derived from sensor signal data.

b. "Pre-Determined Mathematical Model May Include Patient Data or Absorbent Article Data

The pre-determined mathematical model may also include variables that reflect data collected by the user. For example, the "pre-determined mathematical model" may include variables that reflect data "influenc[ing] the patient's continence function," JA0018 at 9:13-17, such as a patient's "fluid and food intake," *Id.* at 9:13-17, as well as patient weight and age, *id.* at 10:6-8 (independent variables of Eq.1). Likewise, the pre-determined mathematical model may include variables that relate to the absorbent article. JA0017 at 8:32-41 ("volume, type or brand of the diaper/garment, and the location of the sensors embedded therein"). Data pertaining to these variables come from beyond the sensor signal data as they are "collected" by a user-monitor and applied to the system for consideration by the pre-determined mathematical model. *Id.* at 9:13-17.

The specification discloses Eq. 1 as a nonlimiting example of an equation to estimate volume of exudate that includes patient data such as weight and age. *Id.* at 10:1-15. However, Eq. 1 is not the only possible equation to include at least one variable derived from sensor signal data and may include at least one more variable derived from data about the patient or absorbent article. Indeed, "Eq. 1 is just one example of a mathematical model which may be used to characterise wetness events," and "other models may be derived." *Id.* at 10:12-14. Further, the specification discloses that the pre-determined mathematical model can take on forms other than equations, including but not limited to databases, graphs, and lookup tables. JA0021 at 15:56-62.

c. Adjustable parameters

Lastly, the specification discloses that the system is agnostic to the initial parameters selected. JA0018 at 9:19-31. Through the use of regression analysis, the system can be used to correlate any data point to a patient's continence habits and devise an appropriate parameter to characterize the event. If the system determines that a variable derived from data has little or no correlation to observation data, the value of the parameter associated with said variable will approach zero through regression analysis rendering the variable marginal or obsolete. As such, the system is designed to determine which data provides the best characterization of a wetness event.

Accordingly, the specification provides ample support for the conclusion that the term "pre-determined mathematical model" is definite and includes at least one variable derived from sensor signal data, may include at least one variable derived from data collected by a user, and that the system is agnostic to the parameters used for any variable in the predetermined mathematical model.

The law cited by Defendant does not support a finding of indefiniteness. For example, in

Sonix, the Federal Circuit was tasked with determining whether the term of degree "visually negligible" was indefinite. *Sonix,* 844 F.3d at 1376. The Federal Circuit surveyed the relevant case law regarding Section 112 in *Enzo*, *Interval Licensing*, and *Datamize* before determining written description support. *Sonix*, 844 F.3d at 1377-79 (describing the relevant facts of *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed. Cir. 2010); *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014); and *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1348 (Fed. Cir. 2005), *abrogated by Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 134 S. Ct. 2120, 189 L. Ed. 2d 37 (2014)).

> In *Enzo*, for example, the written description included examples of noninterfering structures and the procedures for selecting them; we reasoned that the examples and procedures provided guidance and points of comparison for skilled artisans. The one example provided in the written description at issue in *Interval Licensing*, in contrast, was not accompanied by sufficient detail to render the claim scope reasonably certain. In *Datamize*, the written description did not contain any examples of an "aesthetically pleasing" interface, nor did it "explain what factors a person should consider when selecting a feature" to lead to an aesthetically pleasing result.

Sonix, 844 F.3d at 1378-79 (citations omitted). The Federal Circuit then found that the specification of the asserted patent in *Sonix* provided a "level of detail closer to that provided in *Enzo*" because "visually negligible" was supported by at least one exemplary design, requirements, and two specific examples. *Sonix*, 844 F.3d at 1379.

Mantissa Corp. and *dunnhumby USA*, relied upon by the Defendant, are not applicable here. In *Mantissa Corp.,* the court held the term "transaction partner" indefinite after finding it was

first introduced via preliminary amendment without any written description support. 2022 WL 1487577, at *7. Likewise, in *dunnhumby USA, LLC v. emnos USA Corp.* the court held the term "selection of a query type" indefinite after finding (i) the term was added during prosecution to overcome the PTO's rejections without explanation during prosecution for its inclusion and without "direction as to the meaning of query type" from the intrinsic record, and (ii) the extrinsic record provided for multiple plausible meanings. 2015 WL 1542365, at *15-18 (N.D. Ill. April 1, 2015).

Like the terms at issue in *Enzo* and *Sonix*, the term "pre-determined mathematical model" is not indefinite because there is ample written description support in the specification, which appeared in the original application. Further, the specification of the '529 Patent provides as an example Eq. 1, which includes at least one variable derived from sensor signal data and at least one based on data about the patient collected by the user. The specification also provides examples of the types of sensors that may be used with exudate, the types of sensor signal data that may be used by the pre-determined mathematical model, and different types of relevant data that may be collected by the user about the patient or about the absorbent article. Lastly, a purpose of the claimed invention is to formulate the parameters associated with each variable. This is not a situation where the term was added to overcome the prior art without specification support or explanation. *See*, *Mantissa Corp.*, 2022 WL 1487577, at *7; *dunnhumby USA,* 2015 WL 1542365, at *15-18. The term "pre-determined mathematical model" has ample support in the specification to provide a POSA with the objective scope of the term as used in claim 1 of the '529 Patent. *Sonix*, 844 F.3d at 1378-79.

ii. Defendant's Construction Impermissibly Reads Limitations from the Specification into the Claims

Defendant seeks to limit the construction of "pre-determined mathematical model" to "one or more equations with parameters that are calculated and recalculated based on sensor signal data." Defendant's construction should be rejected for the following reasons.

First, the term "equation" is an unnecessarily narrow substitute for "mathematical model." "[E]quation" may be understood by a factfinder as limited to a function or formula, and there is no support in the specification or prosecution history for such a limit. In fact, the specification clearly teaches that an equation is merely a preferred embodiment of a pre-determined mathematical model. JA0021 at 15:56-62 (including databases, graphs and look up tables). Regarding the prosecution history, as described above and is clear from a review of the examiner's rejection and applicants' response, the arguments before the USPTO did not relate to the scope of the term "model." Instead, applicants argued that Panopoulos' system merely detected the occurrence of a wetness event from sensor signal data and that Panopoulos did not disclose or teach either (i) the use of sensor signal data to determine the parameters of the pre-determined mathematical model, or (ii) the application of the pre-determined mathematical model to characterize the wetness event. JA00843. This prosecution history should not be used to limit the scope of "mathematical model" to "equations" because it is not a clear disclaimer of other types of models. Accordingly, there is no support for the Defendant's substitution of "mathematical model" with "equations."

Second, Defendant's requirement of recalculations in its construction is not warranted. As taught in the specification of the '529 Patent, recalculations depend upon the confidence level achieved after a prior calculation. *See*, JA0018 at 9:25-31. If the first calculation results in a pre-determined mathematical model that meets the objective criteria set by a user-monitor, no recalculations are necessary. *Id.* Otherwise, "[t]he same method may be applied to re-calculate parameters of the model." A POSA reading this teaching together with claim 1 would understand

that recalculating the parameters of the pre-determined mathematical model are not a necessary element of claim 1. The prosecution history does not alter this conclusion. Applicants' arguments pointing out that neither Bergman nor Panopoulos teach the calculation of pre-determined mathematical model based on sensor signal data, let alone the recalculation of the pre-determined mathematical model. In that light, applicants' use of the term "recalculate" in tandem with "calculate" can be viewed as a reiteration of the point that neither Bergman nor Panopoulos teach the calculation of the pre-determined mathematical model based on sensor signal data. Thus, there is no clear disclaimer from the prosecution history. Defendant's attempt to read into the term the limitation "recalculate" based on preferred embodiments and applicants' arguments are improper. *Liebel–Flarsheim Co.,* 358 F.3d at 906.

Third, the limit of "with parameters that are calculated… based on sensor signal data" is duplicative of claim language surrounding the term "pre-determined mathematical model" and would only serve to confuse the fact finder. *See*, JA0023 at 19:49-59. For example, if the parameters of the pre-determined mathematical model have already been calculated by virtue of the claim construction, the second wherein clause of claim 1 could be interpreted to require a recalculation of the parameters.

For at least these reasons, the Court should reject Defendant's construction. Instead, the plain and ordinary construction is sufficient to describe the term "pre-determined mathematical model" without injecting limitations regarding how the pre-determined mathematical model is devised.

B. Term #2: "sensor signals"

Plaintiffs' Construction	Defendant's Construction
No construction necessary, plain-and-ordinary meaning.	Signals from a sensor representing information about a user's absorbent article.

Defendant's construction unnecessarily limits the construction of "sensor signals" to

represent "information about a user[-patient]'s absorbent article." The '529 Patent describes in replete detail and claims that sensor signals are used to characterize a wetness event. Information representing the user-patient, the exudate, or the absorbent article are indirectly correlated from the sensor signals via the pre-determined mathematical model. Accordingly, the sensor signals do not necessarily represent information about a user's absorbent article.

Looking to claim 1, notably missing is a "user" and an "absorbent article." Claim 1 requires no more than an input, a processor, and a user interface. As described in the specification, the claimed invention is a system applied to a sensor arranged in an absorbent article to characterize a wetness event. The specification teaches the use of sensors capable of detecting a feature associated with wetness events such as, but not limited to, conductivity. JA0017 at 7:52-54; ("In one embodiment, presence of moisture is indicated by an increase in conductivity between spaced electrodes as a result of moisture forming a conductive bridge between them."); *see also*, JA0015 at 3:38-44; JA0016 at 5:30-33 ("The sensor may include sensor elements for detecting one or more of electrical conductivity, temperature, pressure, pH, odour, gas and presence of a biological or chemical marker in exudate and location of exudate."); JA0017 at 7:55-8:2; JA0019 at 12:4-11 ("The sensor 502 has a sensor element (shown in broken lines) which exhibits a change in conductivity when moisture is present, although other variables such as temperature could be used to detect moisture, as indicated in FIG. 6."). For example, in one embodiment, sensors measure temperature over time, generating a set of data points representable in a graph such as that found in Fig. 6. JA0008; JA0019 at 12:11-23. A POSA reading the specification of the '529 Patent would understand that sensor signals represent a response to a condition "detect[ed]" by the "sensor elements." JA0016 at 5:30-33 ("The sensor may include sensor elements for detecting one or more of …"). The specification then teaches that the system may use sensor signal data, such as but not

limited to the "area under a sensor signal curve, highest sensor signal value in a predetermined time period, maximum value of a leading edge of the sensor signal, rate of decay of sensor signal after a leading edge," etc., JA0017 at 8:49-61, to "derive variables … for use in a mathematical model for characterising a wetness event," JA0015 at 3:35-38. Defendant's citations to the specification describe the sensor signals in terms of wetness events and not in terms of the user-patient or absorbent article. *See* Opening Brief, pp. 9-12.

Defendant's construction also conflates sensor signal data with information about the patient and the absorbent article which do not come from sensor signal data. As discussed in detail above, *supra* IV.a, the pre-determined mathematical model (i) contains a variable derived from sensor signal data, and (ii) *may* contain one or more variables derived from data collected by the user-monitor about the user-patient or the absorbent article. By construing sensor signals to necessarily include data about the user-patient and/or the absorbent article, Defendant unnecessarily limits the scope of claim 1.

Further, Defendant's construction relies on preferred embodiments and applications of the claimed invention to limit the scope of sensor signals to a particular patient and absorbent article. Reading these limitations from preferred embodiments into the claim violates one of the tenets of claim construction. *Liebel–Flarsheim Co.,* 358 F.3d at 906. Defendant argues that the "pre-determined mathematical model is created using a training period of the patient being monitored" based on disclosure regarding a method of training that includes a specific patient. Opening Brief, p. 10 (citing JA0018 at 9:9-17); *see also*, *id.* (citing to teachings in the specification that apply the system to derive a voiding schedule as applied to a single individual), *id.* (citing to teachings in the specification describing how sensors can be arranged in an article), *id.* at 11-12 (citing to teachings in the specification describing how the system can be used to monitor a particular

individual). However, this disclosure provides the public with one example of an application of the claimed invention, and reading into claim 1 limitations from that teaching is improper when the specification also teaches a much broader scope. *Liebel–Flarsheim Co.,* 358 F.3d at 906. For example, the summary of the invention broadly describes a system that at a minimum includes a pre-determined mathematical model with at least one variable based on sensor signal data. E.g., JA0015 at 3:35-38, 3:54-56. Thereafter, the specification teaches, "[p]referably, the processor is adapted to execute an algorithm to *reconfigure* one or more mathematical models for use with one or more of a particular individual being monitored, a different sensor type and a different absorbent article type otherwise." JA0015 at 4:23-26 (emphasis added). From this disclosure a POSA would understand that an initial model may be configured in one setting, such as a controlled lab setting, and "reconfigure[d]" in another, such as on a user-patient. *Id.* By skipping over these details and jumping to the preferred embodiments, Defendant treats the POSA like an "automaton" capable only of implementing preferred embodiments and incapable of drawing "inferences" or employing "creative steps" reasonably anticipated of a POSA. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 & 421 (2007).

Accordingly, there is no support for the construction "signals from a sensor representing information about a user's absorbent article" and the court should reject Defendant's construction. Instead, a plain and ordinary construction of the term "sensor signal" is sufficient in the context of the specification and patent claims.

C. Term #3: "an algorithm to analyze"

Plaintiffs' Construction	Defendant's Construction
No construction necessary, plain-and-ordinary meaning.	"solving one or more equations using the sensor signals and doing more than converting, transposing, or using a look up table on the sensor signals"

Defendant's construction of the term "an algorithm to analyze" should be rejected because the construction restricts the term to "one or more equations" when "algorithm" is broader in scope, contradicts the specification of the '529 Patent, and is based on a mischaracterization of the prosecution history.

The term "an algorithm to analyze" should not be limited to "solving one or more equations." Meriam-Webster broadly defines "algorithm" as "a step-by-step procedure for solving a problem or accomplishing some end." Appendix 1. According to claim 1, the end accomplished by the analyzing algorithm is the characterization of a wetness event by applying sensor signals to the pre-determined mathematical model. JA0023 at 19:49-53. The specification describes the mathematical model broadly to include many forms. *See*, JA0021 at 15:60-62 ("The models may be embodied in any form including mathematical models as described above, graphs or look up tables."). Defendant ignores this disclosure and instead relies on embodiments that use equations to form the basis of the pre-determined mathematical model.

Further, Defendant mischaracterizes the prosecution history to suggest that the applicants "disclaim[ed] any interpretation where the algorithm does anything less than 'using the sensor signals and doing more than converting, transposing, or using a look up table on the sensor signals.'" Opening Brief, pp. 13-14. However, Defendant fails to point to any "words or expressions of manifest exclusion or restriction" and instead misconstrues the arguments. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002). Defendant leaves out context necessary to understand the prosecution history. Opening Brief, p. 13 (citing to a portion of JA0843 and omitting "(a)"). Notably missing from Defendant's explanation is "(a) employs a mathematical model which has been pre-determined based on data previously received by that system." JA0843. When this context is added, it is clear that during prosecution applicants argued that Bergman

"merely" applies a model to sensor signal, but that the model is not based on sensor signal data. Counter to Defendant's argument, applicants even argued that the model's format is immaterial so long as the parameters of model are devised by the system:

> Whilst it may be the case that the conversion [taught in Panopoulos] is established by applying a mathematical equation, Applicant notes that any such equation is pre-programmed into the calibration ROM. There is no teaching or suggestion in Panopoulos that a mathematical model is determined *by the system*, based on previously received sensor data.

JA0845 (emphasis original). Here, applicants specifically noted that the mathematical model taught in Panopoulos, regardless of its format, is not determined by the system.

Accordingly, applicants did not disclaim "converting, transposing, or using a look up table" for the algorithm to analyze sensor signals for the characterization of a wetness event, and the Court should not adopt the Defendant's construction. Instead, a plain and ordinary construction is sufficient in the context of the patent. As mentioned above, an "algorithm" is "a step-by-step procedure for solving a problem or accomplishing some end." Appendix 1. The full limitation in which the term resides reads: "wherein the processor executes an algorithm to analyze the one or more sensor signals by applying the one or more received sensor signals to a pre-determined mathematical model to characterize a wetness event in an absorbent article." JA0023 at 19:49-53. This language is sufficient to infer that the term "algorithm to analyze" means a step by step process for the characterization of a wetness event by applying sensor signals to a pre-determined mathematical model. No additional construction is needed for the fact finder to understand this term.

D. Term #4: "the system has devised the pre-determined mathematical model"

Plaintiffs' Construction	Defendant's Construction
No construction necessary, plain-and-ordinary meaning.	The system creates the pre-determined mathematical model without it being uploaded to the system.

Defendant's construction unnecessarily limits the construction of "system" to a single unit that must both devise a pre-determined mathematical model and characterize a wetness event. Like before, Defendant's position is based improperly upon preferred embodiments teaching the use of a system to create a pre-determined mathematical model. *Liebel–Flarsheim Co.*, 358 F.3d at 906.

Starting with the grammatical structure of claim 1, Defendant argues that "it must be *the same* moisture monitoring system for monitoring wetness in one or more absorbent articles' to have 'devised the pre-determined mathematical model,' and not some *other system* that creates the model, which is then merely uploaded to the system." Opening Brief, p. 15 (emphasis original); see also, *id.* at p. 16 ("The figures likewise confirm the system's creation of the pre-determined mathematical model rather than mere application of a previously uploaded model."). Such a limitation is not warranted because case law supports the conclusion that "system" does not necessarily imply a single unit performing all functions of a claim. For example, in *Rowe Int'l Corp. v. Ecast, Inc.*, the court found "there is nothing in the claim language that requires any given processor to perform all of the listed functions." 586 F. Supp. 2d 924, 949 (N.D. Ill. 2008). *See also*, *Ford Motor Co. v. Versata Software, Inc.*, No. 15-11624, 2016 WL 8315738, at *18 (E.D. Mich. Nov. 7, 2016) (construing the term "system" to mean "a collection of components, combined to form a particular product or service."); *USHIP Intell. Properties, LLC v. United States*, 98 Fed. Cl. 396, 413, *on reconsideration in part,* 102 Fed. Cl. 326 (2011), and *aff'd,* 714 F.3d 1311 (Fed. Cir. 2013) ("Although these terms are used throughout the specification, when used in reference to the invention, they do not explicitly limit the terms to 'single apparatuses.'"); *Paragon Sols., LLC v. Timex Corp.*, 566 F.3d 1075, 1087 (Fed. Cir. 2009) (construing "display unit" to mean "a structure or set of structures" that perform a set of functions). As was the case in *Rowe*, there is nothing in claim 1 of the '529 Patent that requires both functions (i.e., to devise a pre-determined

mathematical model and to characterize an event based on that pre-determined mathematical model) to be performed by a single unit.

Defendant supports its position with reference to preferred embodiments taught in the specification describing how to use and train a system on a single user-patient. Opening Brief, pp. 16-18. Defendant overlooks the full scope of the specification. In particular, the specification teaches, "*[p]referably*, the processor is adapted to execute an algorithm to reconfigure one or more mathematical models *for use with one or more* of a particular individual being monitored, a different sensor type and a different absorbent article type otherwise." JA0015 at 4:23-26. (emphasis added). A POSA reading this disclosure would understand that the system can include one unit to devise a pre-determined mathematical model, another unit to characterize the wetness event, and would further understand that for the second unit to use the pre-determined mathematical model devised by the first unit, the pre-determined mathematical model must be transferred from the first unit to the second. *Id*. For example, the system may be used in a controlled laboratory setting to devise a mathematical model. Once the model is devised, it may be transferred or uploaded to additional units that use the pre-determined mathematical model to characterize a subsequent wetness event. Thus, neither the term "system" nor the term "the system has devised the pre-determined mathematical model" should be limited to the same identical system or unit to both devise a pre-determined mathematical model and characterize a wetness event based on that pre-determined mathematical model.

Defendant's construction also suggests that the pre-determined mathematical model is generated by the system without any previous input. Opening Brief, p. 16 ("The figures likewise confirm the system's creation of the pre-determined mathematical model rather than mere application of a previously uploaded model."). However, this is not the case. The specification

teaches that "the algorithm may be programmed in software or in hardware using a range of different techniques and languages known to a person skilled in the relevant art." JA0017. Additionally, the specification teaches that the pre-determined mathematical model may take many forms including equations, databases of event triggers, graphs, and look up tables, JA0021 at 15:56-62, and that "[v]ariables derived from the sensor signals may be *selected*…" JA0015 at 3:45-46 (emphasis added). Further, the specification teaches that the parameters of any variable selected are devised by the system through regression analysis based on observation data. JA0018 at 9:18-31. A POSA reading the specification would understand that in one embodiment the system may come preloaded with a pre-determined mathematical model, the parameters of which are calculated and refined through use and regression analysis.

The Court should adopt the plain and ordinary meaning of the term "the system has devised the pre-determined mathematical model" because a POSA would understand from the full disclosure that the pre-determined mathematical model is provided to the processor, while Defendant's construction is limited to a preferred embodiment disclosed in the specification.

E. Term #5: "using sensor signal data previously received by the system"

Plaintiffs' Construction	Defendant's Construction
No construction necessary, plain-and-ordinary meaning.	The system uses sensor signal data previously received by the system to create the predetermined mathematical model.

Defendant's construction should be rejected because it simply reorders the actual claim language in an attempt to limit the system to an individual unit that must both (1) develop the parameters of the pre-determined mathematical model, and (2) characterize a wetness event. *Liebel–Flarsheim Co.,* 358 F.3d at 906.

Defendant's construction adds nothing to the meaning of this term, especially when compared to the surrounding claim language, and as such should be rejected. The full subclause in

which the disputed term resides reads as follows: "wherein the system has devised the pre-determined mathematical model *using sensor signal data previously received by the system*." JA0023 at 19:54-56 (term in dispute emphasized). Defendant's construction is merely a rearrangement of parts plus the substitution of "devise" with "create" without any objectively perceivable detail included not already understood after reading the full subclause. For this reason, the Court should adopt a plain and ordinary construction.

Defendant once again seeks to limit "system" to an individual unit that must both (a) devise the parameters of the pre-determined mathematical model on a patient with an absorbent article, and (b) characterize a wetness event based on the pre-determined mathematical model devised. Defendant even claims applicants "disavowed any interpretation" beyond its construction because the "specification is consistent" and "**only** describes a pre-determined mathematical model that is created with sensor signal data from the user's absorbent article." Opening Brief, p. 20 (emphasis original). Absent "words or expressions of manifest exclusion or restriction," courts must follow the language of the claims and not the written description. *Teleflex,* 299 F.3d at 1327. Defendant cannot point to any words from applicants that expressly disavows a disjointed system wherein one unit devises the pre-determined mathematical model and another unit utilizes that pre-determined mathematical model to characterize subsequent wetness events. Further, as described above, *supra* IV.D, case law supports the conclusion that "system" as claimed in claim 1 does not necessarily imply a single unit to perform all functions. As was the case in *Rowe*, there is nothing in claim 1 of the patent in suit that requires all functions (i.e., to devise a pre-determined mathematical model and to characterize an event based on the pre-determined mathematical model) to be performed by a single unit. *Rowe,* 586 F. Supp. 2d at 949.

Counter to Defendant's claim that the patent "**only** describes a pre-determined

mathematical model that is created with sensor signal data from the user's absorbent article," Opening Brief, p. 20 (emphasis original), the specification teaches otherwise. In particular, the summary of the invention broadly describes a system that at a minimum includes a pre-determined mathematical model with at least one variable based on sensor signal data. E.g., JA0015 at 3:35-38, 3:54-56. Thereafter, the specification discloses, "[p]referably, the processor is adapted to execute an algorithm to *reconfigure* one or more mathematical models *for use with one or more* of a particular individual being monitored, a different sensor type and a different absorbent article type otherwise." JA0015 at 4:23-26.

As discussed above, *supra* IV.D, it would be well within the understanding of a POSA that the system is used in one setting to devise a pre-determined mathematical model and then used in a subsequent setting to use the pre-determined mathematical model to characterize a subsequent wetness event, even if that system was reconfigured to a new user-patient, sensor, or absorbent article.

Defendant's characterization of the prosecution history provides no support. The applicants' arguments were focused on traversing prior art that did not use sensor signal data to configure a mathematical model for the characterization of a wetness event. There is no specific disavowal or claim that a single unit must both devise the pre-determined mathematical model and characterize a wetness event.

Hence, there is no support for Defendant's construction, and it should be rejected.

F. Term #6 - "to characterize a wetness event"/"to characterise a wetness event"/"characterizing a wetness event"

Plaintiffs' Construction	Defendant's Construction
No construction necessary, plain-and-ordinary meaning.	To (a) state if a wetness event occurred, and (b) to provide additional information about the wetness event.

Plaintiffs dispute this construction because it is not necessary in all instances to state if a wetness event occurred and therefore not necessary to provide "additional" information about the wetness event. Plaintiffs are willing to accept as a construction of this term "to provide information about a wetness event," but such a construction does not provide for more than the term itself, and as such Plaintiffs seek a plain and ordinary construction.

Depending upon sensor selection, it is not necessary in all instances for the characterization of a wetness event to include a statement that a wetness event occurred. For example, the specification teaches that an absorbent article may be fitted with different sensor types. JA0018. By extension, an absorbent article could include one sensor, such as a conductivity sensor, to state if a wetness event occurred and provide additional information such as volume about the wetness event. The same article can also include another sensor, such as one to detect biomarkers, only to provide information about the wetness event itself. Thus, it is not necessary in all instances for the characterization of a wetness event to include both (a) statement that a wetness event occurred, and (b) additional information.

V. CONCLUSION

In conclusion, each of Defendant's positions should be rejected, and the Court should adopt a plain and ordinary construction for each term.

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Respectfully submitted,

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